

1 AN ACT concerning health facilities.

2 Be it enacted by the People of the State of Illinois,
3 represented in the General Assembly:

4 Section 1. Short title. This Act may be cited as the
5 End Stage Renal Disease Facility Act.

6 Section 5. Definitions. As used in this Act:

7 "Committee" means the End Stage Renal Disease Advisory
8 Committee.

9 "Department" means the Department of Public Health.

10 "Dialysis" means a process by which dissolved substances
11 are removed from a patient's body by diffusion from one
12 fluid compartment to another across a semipermeable membrane.

13 "Dialysis technician" means an individual who is not a
14 registered nurse or physician and who provides dialysis care
15 under the supervision of a registered nurse or physician.

16 "Director" means the Director of Public Health.

17 "End stage renal disease" means the stage of renal
18 impairment that appears irreversible and permanent and that
19 requires a regular course of dialysis or kidney
20 transplantation to maintain life.

21 "End stage renal disease facility" means a facility that
22 provides dialysis treatment or dialysis training to
23 individuals with end stage renal disease.

24 "Licensee" means an individual or entity licensed by the
25 Department to operate an end stage renal disease facility.

26 "Nurse" means an individual who is licensed to practice
27 nursing under the Nursing and Advanced Practice Nursing Act.

28 "Patient" means an individual receiving treatment from an
29 end stage renal disease facility.

30 "Person" means any individual, firm, partnership,
31 corporation, company, association, or other legal entity.

1 "Physician" means an individual who is licensed to
 2 practice medicine in all of its branches under the Medical
 3 Practice Act of 1987.

4 Section 10. License required. Except as provided by
 5 this Act, no person shall open, manage, conduct, offer,
 6 maintain, or advertise an end stage renal disease facility
 7 without a valid license issued by the Department. All end
 8 stage renal disease facilities in existence as of the
 9 effective date of this Act shall obtain a valid license to
 10 operate within one year after the effective date of this Act.

11 Section 15. Exemptions from licensing requirement. The
 12 following facilities are not required to be licensed under
 13 this Act:

- 14 (1) a home health agency licensed under the Home
 15 Health Agency Licensing Act that provides dialysis
 16 services in the home under the supervision of a nurse;
- 17 (2) a hospital licensed under the Hospital
 18 Licensing Act or the University of Illinois Hospital Act;
- 19 (3) the office of a physician, unless the office is
 20 used primarily as an end stage renal disease facility;
 21 and
- 22 (4) a facility licensed under the Nursing Home Care
 23 Act.

24 Section 20. Issuance and renewal of license.

25 (a) An applicant for a license under this Act shall
 26 submit an application on forms prescribed by the Department.

27 (b) Each application shall be accompanied by a
 28 non-refundable license fee, as established by the rules of
 29 the Department.

30 (c) Each application shall contain evidence that there
 31 is at least one qualified physician responsible for the

1 medical direction of the facility and that each dialysis
2 technician on staff has completed a training program as
3 required by this Act.

4 (d) The Department may grant a temporary initial license
5 to an applicant. A temporary initial license expires on the
6 earlier of (i) the date the Department issues or denies the
7 license or (ii) the date 6 months after the date the
8 temporary initial license was issued.

9 (e) The Department shall issue a license if, after
10 application, inspection, and investigation, it finds that the
11 applicant meets the requirements of this Act and the
12 standards adopted pursuant to this Act. The Department may
13 include participation as a supplier of end stage renal
14 disease services under Titles XVIII and XIX of the federal
15 Social Security Act as a condition of licensure.

16 (f) The license is renewable annually after submission
17 of (i) the renewal application and fee and (ii) an annual
18 report on a form prescribed by the Department that includes
19 information related to quality of care at the end stage renal
20 disease facility. The report must be in the form and
21 documented by evidence as required by the rules adopted by
22 the Department.

23 Section 25. Minimum staffing. An end stage renal
24 disease facility shall be under the medical direction of a
25 qualified physician experienced in renal disease treatment,
26 as required for licensure under this Act. Additionally, at a
27 minimum, every facility licensed under this Act shall ensure
28 that whenever patients are undergoing dialysis all of the
29 following are met:

30 (1) one currently licensed physician, registered
31 nurse, or licensed practical nurse experienced in
32 rendering end stage renal disease care is physically
33 present on the premises to oversee patient care;

1 (2) adequate staff is present to meet the medical
 2 and non-medical needs of each patient, as provided by
 3 this Act and the rules adopted pursuant to this Act, in a
 4 ratio of at least one staff member to every 3 patients
 5 receiving end stage renal disease services at the same
 6 time; and

7 (3) if the facility offers self-care dialysis
 8 training, a qualified nurse is in charge of that
 9 training.

10 Section 30. Minimum standards.

11 (a) The rules adopted pursuant to this Act shall contain
 12 minimum standards to protect the health and safety of a
 13 patient of an end stage renal disease facility, including
 14 standards for:

15 (1) the qualifications and supervision of the
 16 professional staff and other personnel;

17 (2) the equipment used by the facility to insure
 18 that it is compatible with the health and safety of the
 19 patients;

20 (3) the sanitary and hygienic conditions in the
 21 facility;

22 (4) quality assurance for patient care;

23 (5) clinical records maintained by the facility;

24 (6) design and space requirements for the facility
 25 to insure safe access by patients and personnel and to
 26 insure patient privacy;

27 (7) indicators of the quality of care provided by
 28 the facility; and

29 (8) water treatment and reuse by the facility.

30 (b) The standards described in item (8) of subsection
 31 (a) of this Section shall apply only (i) to a facility that
 32 initiates the provision of end stage renal disease services
 33 on or after January 1, 2003 or (ii) to the area of a facility

1 affected by design and space modifications or renovations
2 completed after January 1, 2004.

3 Section 35. Training; minimum requirements. An end
4 stage renal disease facility shall establish and implement a
5 policy to ensure appropriate training and competency of
6 individuals employed as dialysis technicians within the
7 licensed facility. The policy shall, at a minimum, define
8 the acts and practices that are allowed or prohibited for
9 such employees, establish how training will be conducted, and
10 illustrate how initial competency will be established. Proof
11 of initial and annual competency testing shall be maintained
12 in the personnel file of each employee and shall be made
13 available to the Department upon request. An individual may
14 not act as a dialysis technician in an end stage renal
15 disease facility unless that individual has been trained and
16 competency tested in accordance with this Act and the rules
17 adopted thereunder. Persons training to act as dialysis
18 technicians must be under the direct supervision of a
19 physician or an appropriately trained nurse.

20 Section 40. Inspections.

21 (a) The Department, whenever it deems necessary, may
22 conduct an inspection, survey, or evaluation of an end stage
23 renal disease facility to determine compliance with licensure
24 requirements and standards or a plan of correction submitted
25 as a result of deficiencies cited by the Department.

26 (b) An inspection conducted under this Section shall be
27 unannounced.

28 (c) Areas in a facility identified as deficient in
29 compliance with the requirements of this Act or the standards
30 adopted under this Act shall be presented to the facility.

31 (d) Upon completion of each inspection, survey, or
32 evaluation, the appropriate Department personnel who

1 conducted the inspection, survey, or evaluation shall submit
2 a copy of their report to the licensee upon exiting the
3 facility, and shall submit the actual report to the
4 appropriate regional office. The report and any
5 recommendation for action by the Department under this Act
6 shall be sent to the Department's central office together
7 with a plan of correction from the facility. The plan of
8 correction may contain related comments or documentation
9 provided by the licensee that may refute findings in the
10 report, explain extenuating circumstances that the facility
11 could not reasonably have prevented, or indicate methods and
12 timetables for correction of deficiencies described in the
13 report. A licensee has 10 days to submit a plan of
14 correction.

15 (e) Violations shall be determined under this Section no
16 later than 60 days after completion of each inspection,
17 survey, evaluation, or plan of correction.

18 (f) The Department shall maintain all inspection,
19 survey, or evaluation reports for at least 5 years in a
20 manner accessible to the public.

21 Section 45. Civil penalties.

22 (a) The license of a facility that is in violation of
23 this Act or any rule adopted thereunder may be subject to the
24 penalties or fines levied by the Department as specified in
25 this Section.

26 (b) A Class I violation is one that the Department
27 determines presents an imminent danger to the patients of the
28 facility or a substantial probability that death or serious
29 physical harm could result therefrom. A physical condition
30 or one or more practices, means, methods, or operations in
31 use in a facility may constitute such a violation. The
32 condition or practice constituting a Class I violation shall
33 be abated or eliminated immediately unless a fixed period of

1 time, as stipulated by the Department, is required for
 2 correction. Each day such a violation exists after
 3 expiration of the stipulated time shall be considered a
 4 subsequent violation. The civil penalty for a Class I
 5 violation is as follows:

6 (1) \$1,500 for a first violation within a 24 month
 7 period;

8 (2) \$3,000 for a second violation within a 24 month
 9 period;

10 (3) \$5,000 for a third violation within a 24 month
 11 period; and

12 (4) \$10,000 for a fourth or subsequent violation
 13 within a 24 month period.

14 (c) A Class II violation is one that the Department
 15 determines has a direct or immediate relationship to the
 16 health, safety, or security of the facility's patients, but
 17 is not a Class I violation. The citation for a Class II
 18 violation shall specify the time within which the violation
 19 is required to be corrected. Each day such a violation
 20 exists after the expiration of the specified time shall be
 21 considered a subsequent violation. The civil penalty for a
 22 Class II violation is as follows:

23 (1) \$250 for a first violation within a 24 month
 24 period;

25 (2) \$500 for a second violation within a 24 month
 26 period;

27 (3) \$1,000 for a third violation within a 24 month
 28 period;

29 (4) \$2,500 for a fourth violation within a 24 month
 30 period; and

31 (5) \$5,000 for a fifth or subsequent violation
 32 within a 24 month period.

33 (d) A Class III violation is one that is not classified
 34 as serious by the Department or that is against the best

1 practices as interpreted by the Department. The citation of
 2 a Class III violation shall specify a time within which the
 3 violation is required to be corrected. Each day such a
 4 violation exists after the expiration of the specified time
 5 shall be considered a subsequent violation. A civil penalty
 6 shall not be assessed for a first violation within a 24 month
 7 period. The civil penalty for a Class III violation is as
 8 follows:

9 (1) \$200 for a second violation within a 24 month
 10 period;

11 (2) \$500 for a third violation within a 24 month
 12 period;

13 (3) \$750 for a fourth violation within a 24 month
 14 period; and

15 (4) \$1,000 for a fifth or subsequent violation
 16 within a 24 month period.

17 (e) For purposes of assessing fines under this Section,
 18 a repeat violation is a violation that has been cited during
 19 one inspection of a facility for which an accepted plan of
 20 correction was not complied with. A new citation is not a
 21 repeat violation unless the licensee is not substantially
 22 addressing the issue routinely throughout the facility.

23 Section 50. Department access to and reproduction of
 24 documents. The Department shall have access to and may
 25 reproduce or photocopy at its cost any books, records, and
 26 other documents maintained by the facility to the extent
 27 necessary to carry out the purposes of this Act and the rules
 28 promulgated under this Act. The Department shall not divulge
 29 or disclose the identity of any patient or other information
 30 prohibited from disclosure by the laws of this State.

31 Section 55. Refusal to allow inspections. Any licensee,
 32 applicant for a license, or person operating what may be an

1 end stage renal disease facility shall be deemed to have
2 given consent to any authorized officer, employee, or agent
3 of the Department to enter and inspect the facility in
4 accordance with this Act. Refusal to permit such entry or
5 inspection shall constitute grounds for denial, nonrenewal,
6 or revocation of a license.

7 Section 60. Denial, suspension, or revocation of
8 license.

9 (a) The Department may deny, suspend, or revoke a
10 license for a violation of this Act or a rule adopted
11 pursuant to this Act.

12 (b) The denial, suspension, or revocation of a license
13 by the Department and the appeal from that action are
14 governed by the Illinois Administrative Procedure Act.

15 (c) Immediately upon the denial, suspension, or
16 revocation of a license, the Department shall notify the
17 applicant or licensee in writing. Notice of the denial,
18 suspension, or revocation shall include a statement of the
19 violations of the Act or rules on which the denial is based
20 and notice of the opportunity for a hearing under the
21 Illinois Administrative Procedure Act. If the applicant
22 desires to contest the Department's action, a written request
23 for a hearing shall be provided to the Department within 10
24 days after receipt of the Department's notice.

25 Section 65. Probationary license. If the applicant has
26 not been previously licensed or if the facility is not in
27 operation at the time application is made, the Department
28 shall issue a probationary license. A probationary license
29 shall be valid for 120 days unless sooner suspended or
30 revoked under this Act. Within 30 days prior to the
31 termination of a probationary license, the Department shall
32 fully and completely inspect the facility and, if the

1 facility meets the applicable requirements for licensure,
2 shall issue a license under this Act. If the Department
3 finds that the facility does not meet the requirements for
4 licensure but has made substantial progress toward meeting
5 those requirements, the license may be renewed once for a
6 period not to exceed 120 days from the expiration date of the
7 initial probationary license.

8 Section 70. Change of ownership.

9 (a) Whenever ownership of a facility is transferred from
10 the person named in the license to any other person, the
11 transferee must obtain a new probationary license. The
12 transferee shall notify the Department of the transfer and
13 apply for a new license at least 30 days prior to final
14 transfer.

15 (b) The transferor shall notify the Department at least
16 30 days prior to final transfer. The transferor shall remain
17 responsible for the operation of the facility until such time
18 as a license is issued to the transferee.

19 (c) The license granted to the transferee shall be
20 subject to any plan of correction submitted by the previous
21 owner and approved by the Department and any conditions
22 contained in a conditional license issued to the previous
23 owner. If there are outstanding violations and no approved
24 plan of correction has been implemented, the Department may
25 issue a conditional license and plan of correction as
26 provided in this Act.

27 (d) The transferor shall remain liable for all penalties
28 assessed against the facility that are imposed for violations
29 occurring prior to transfer of ownership.

30 Section 75. Access to information. The following
31 information is subject to disclosure to the public by the
32 Department:

1 (1) records of license inspections, surveys, and
2 evaluations of facilities; and

3 (2) complaints and complaint investigation reports,
4 except that a complaint or complaint investigation report
5 shall not be disclosed to a person other than the
6 complainant or complainant's representative before it is
7 disclosed to a facility and except that a complainant's
8 or patient's name shall not be disclosed.

9 Section 80. Information available for public inspection.

10 (a) A facility shall post in plain view of the public
11 (i) its current license, (ii) a description, provided by the
12 Department, of complaint procedures established under this
13 Act, and (iii) the name, address, and telephone number of a
14 person authorized by the Department to receive complaints.

15 (b) A facility shall make the following information or
16 documents available upon request for public inspection:

17 (1) a copy of any order pertaining to the facility
18 issued by the Department or a court;

19 (2) a complete copy of every inspection report of
20 the facility received from the Department during the past
21 5 years;

22 (3) a copy of every order pertaining to the
23 facility issued by the Department or a court during the
24 past 5 years;

25 (4) a description of the services provided by the
26 facility and the rates charged for those services;

27 (5) a copy of the statement of ownership required
28 by this Act;

29 (6) a record of personnel employed or retained by
30 the facility who are licensed, certified, or registered
31 by the Department of Professional Regulation; and

32 (7) a complete copy of the most recent inspection
33 report of the facility received from the Department.

1 Section 85. End Stage Renal Disease Advisory Committee.

2 (a) The Director shall appoint an End Stage Renal
3 Disease Advisory Committee to advise and consult with the
4 Director in the administration of this Act. The Committee
5 shall be composed of the following members:

6 (1) 3 members who represent end stage renal disease
7 facilities, one of whom shall represent not-for-profit
8 facilities, one of whom shall represent for-profit
9 facilities, and one of whom shall represent
10 institution-based facilities;

11 (2) 2 members who are physicians licensed to
12 practice medicine in all its branches;

13 (3) one member who is a board-certified
14 nephrologist;

15 (4) one member who represents licensed hospitals;

16 (5) one member who is a registered professional
17 nurse with experience treating end stage renal disease;

18 (6) 3 members of the general public, one of whom is
19 currently receiving dialysis.

20 The recommendations of professional organizations may be
21 considered in selecting individuals for appointment to the
22 End Stage Renal Disease Advisory Committee.

23 (b) Each member shall be appointed for a term of 3
24 years, except that of the original members, 3 shall be
25 appointed for a term of one year, 4 shall be appointed for a
26 term of 2 years, and 4 shall be appointed for a term of 3
27 years. The term of office of each of the original appointees
28 shall commence on July 1, 2002. A member appointed to fill a
29 vacancy occurring prior to the expiration of the term for
30 which his or her predecessor was appointed shall be appointed
31 for the remainder of that term.

32 (c) The Committee shall meet as frequently as the
33 Director deems necessary. Committee members, while serving
34 on business of the Committee, shall receive actual and

1 necessary travel and subsistence expenses while so serving
2 away from their places of residence.

3 Section 90. Adoption of rules. The Department shall
4 adopt rules to implement this Act, including requirements for
5 physical plant standards and for the issuance, renewal,
6 denial, suspension, and revocation of a license to operate an
7 end stage renal disease facility.

8 Section 95. Fees. The Department may establish and
9 collect fees in amounts reasonable and necessary to defray
10 the cost of administering this Act. In setting fees under
11 this Act, the Department shall consider setting a range of
12 license and renewal fees based on the number of dialysis
13 stations at the end stage renal disease facility, the patient
14 census, and the average costs involved in surveying the
15 facility.

16 Section 100. Deposit of fees and penalties. Fees and
17 penalties collected under this Act shall be deposited into
18 the End Stage Renal Disease Facility Licensing Fund, which is
19 hereby created as a special fund in the State treasury.
20 Moneys in the Fund may be used, subject to appropriation, by
21 the Department for the administration of this Act.

22 Section 105. The State Finance Act is amended by adding
23 Section 5.545 as follows:

24 (30 ILCS 105/5.545 new)

25 Sec. 5.545. The End Stage Renal Disease Facility
26 Licensing Fund.

27 Section 999. Effective date. This Act takes effect
28 January 1, 2002.